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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,342	02/12/2004	Frederic Nefel	B0884.70074US01	4933

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Lawrence Green
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Boston, MA 02210

EXAMINER

GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/777,342	Applicant(s) NEFTEL, FREDERIC	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's communication of 12/26/2006. After reconsideration of the applicant's arguments the finality of the rejection of the last Office action is withdrawn and prosecution is reopened. See rejection and remarks below. Currently amended and newly added claims 1-24 are pending and stand rejected below.

Response to Arguments

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection. See below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Uber III (U.S. Patent Number 5,843,037, hereafter "Uber"). Uber discloses a multipatient fluid dispensing system and method of injecting liquid under pressure to a patient (see Uber column 1 generally). Uber discloses a method for injecting that comprises the steps of 1.) **providing liquid under pressure to a patent**, via a set of

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tubing with an occlusion system and an upstream regulation system, and 2.) **when the injection is to be stopped closing the regulation system** and 3.) after the closing of the regulation system **closing the first occlusion system**. Uber discloses these steps of providing liquid (described in column 2), and closing the regulation system and later the occlusion system disclosed in column 3). It is evident that Uber would disclose providing the liquid and then stopping the liquid by closing the regulation system and then the occlusion system. For instance (in figure 1) after supplying the fluid, the valve/pump regulation system elements (12, 20, 21 for one example) would be shut off by electrical control system, and then the occlusion system would be shut off (such as rotary valve 27), as described in paragraphs at column 3. The claim limitations of the intermediate segment (Uber element 26 for example) having an intermediate pressure greater than the downstream segment (36 for example) would be evident in operation of the system. Pump 12 would provide a pressure for the system that would be greatest at the upstream end (near 10) and would decrease as the liquid flowed through the system and would least at the end (near patent end 36). This pressure difference would be evident due to the fact that the liquid flows to the patient and not upstream into the reservoir, besides the overall nature of fluid dynamics.

Further the intermediate segment would have a contained intermediate pressure (in supply conduit 26 since oneway valve 25 and rotary valve 27 would seal this segment and maintain a specific intermediate pressure) that would be greater than the downstream end (36) and hence fluid would flow to the end of lower pressure (ie the downstream end). The Uber systems pressure difference between the intermediate

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pressure and the downstream pressure would prevent the upstream flow of liquid even after the injection has stopped (either by stopping the regulation system, occlusion system or both sequentially or simultaneously). It is examiners position that Uber discloses all the steps of the method (1. providing liquid, 2. closing the regulation system, 3. then closing the occlusion system) and these steps are carried out on a structural apparatus similar to the claimed structural apparatus (tubes with regulation system and occlusion system) and that the intermediate/downstream pressure differential would exist and be present in the system as carried out by the Uber method disclosed.

Examiner maintains but clarifies rejections in previous Office action.

Claims 1-2, 4-19, and 21-24, are rejected under 35 U.S.C. 102(b) as being anticipated by Hellman et al. (U.S. Patent Number 5,569,181). Hellman discloses a sterility assurance for a contrast delivery system. Hellman patent discloses a process and apparatus for injection of a multiple number of patients with fluid by selective valving devices and disposable dosing units. Hellman further discloses a method of injecting liquid through a length of tubing with multiple occlusion systems and regulation systems with varying pressures, closing the valved systems at various junctions will stop injection to a patient, the measurement of pressure and providing an output indicative of leakage, and maintaining intermediate pressure through a peristaltic cassette pump, syringe pump, or a gear pump. The method system does include a

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non-return or one-way valve. (see paragraphs beginning from column 3, line 59 to column 7, line 39).

Concerning the claim limitation of the "pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped" would be inherent in the prior art as a functional procedure (or physical occurrence) that occurs as a natural result of the taught operation. The prior art of record discloses all steps of the claimed method (i.e. 1. providing liquid, 2. closing the regulation system, 3. then closing the occlusion system) and these steps are carried out on a structural apparatus similar to the claimed structural apparatus (tubes with regulation system and occlusion system) and that the intermediate/downstream pressure differential would exist and be present in the system as carried out by the Hellman method disclosed.

Claims 1-7, 10-13, and 15-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lichtenstein (U.S. Patent Number 4,464,172). Lichtenstein discloses a computer controlled medical care system for use in the treatment and diagnosis of patients, which provides for either automatic or manual control of a wide variety of medical procedures. Lichtenstein discloses a system of tubing and valves for infusion to a patient, which contains a wide variety of sensors. The system may include one or more sensors for determining pressure and rate of fluid flow within ducts and chambers in the module. Also included may be sensors for invasive or noninvasive determination of intravascular pressures within a patient connected with a module and arrangements

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for gravity flow or pumped flow of fluid between a module and a patient or within the module. The Lichtenstein includes an intermediate segment of tubing with one way valves and various pumps that are monitored and controlled to regulate the pressure and fluid flow to a patient. (see paragraphs beginning at column 7 line 53, to column 12 line 54).

Concerning the claim limitation of the "pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped" would be inherent in the prior art as a functional procedure (or physical occurrence) that occurs as a natural result of the taught operation. The prior art of record discloses all steps of the claimed method (i.e. 1. providing liquid, 2. closing the regulation system, 3. then closing the occlusion system) and these steps are carried out on a structural apparatus similar to the claimed structural apparatus (tubes with regulation system and occlusion system) and that the intermediate/downstream pressure differential would exist and be present in the system as carried out by the Lichenstein method disclosed.

Claims 1-7, 9-13, and 15-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Teirstein (U.S. Patent Number 5,533,978). Teirstein discloses a method and apparatus for uninterrupted delivery of radiographic dye with a syringe manifold. It includes a regulation system for an intermediate section of tubing with a one-way valve. Further Teirstein discloses an air alarm for response to an output of leakage from the intermediate segment, maintenance of pressure in the intermediate section by pumps.

Further Teirstein discloses that injection can be stopped by closing the upstream valving systems and that the pressure in the intermediate section can be monitored (See paragraphs at column 2, line 20 to column 4 line 34, or paragraphs beginning with column 6 line 45, to column 7 line 50).

Concerning the claim limitation of the "pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped" would be inherent in the prior art as a functional procedure (or physical occurrence) that occurs as a natural result of the taught operation. The prior art of record discloses all steps of the claimed method (i.e. 1. providing liquid, 2. closing the regulation system, 3. then closing the occlusion system) and these steps are carried out on a structural apparatus similar to the claimed structural apparatus (tubes with regulation system and occlusion system) and that the intermediate/downstream pressure differential would exist and be present in the system as carried out by the Teirstein method disclosed.

It is examiner's position that the prior art of record does satisfy and anticipate the claims as amended. Namely the limitation of the "pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped" would be inherent in the prior art as a functional procedure (and physical occurrence) that occurs as a natural result of the taught operation. The claims as written do not preclude the mechanical regulation of the system as taught in the prior art of record, from anticipating them, and capable of their

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claimed operation. Although, not the only concern by the examiner, but the “transient pressure difference” as stated in the applicant’s arguments would still anticipate the claims as amended currently. The differences advanced by the applicant’s representative, between the instant invention and the prior art of record are not shown in the language of the “pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped”. This is not a physical step or structural/spatial relationship, this limitation is merely a physical occurrence that would be happening in the methods of the prior art. Even so, in addition to the pressure differences which exist throughout the prior art method, the transient pressure as discussed in the applicant’s argument would exist even when the injection was stopped (even if moments after).

In operation of the prior art methods and systems, the positive pressure upstream would cause the flow of liquid out to the downstream end of lowest pressure after passing through an intermediate section of intermediate pressure. Closing of regulation systems and occlusion systems would not instantly cause these intermediate pressures to not exist.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., non-mechanical pressure control/regulation, and the means for what prevents backflow) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The prior art of record anticipates the pending claims as written because all claim limitations are met and the interpretation of the prior art satisfies all functional, structural, operational and spatial, claim limitations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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